



May 14, 2019

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Comments on Notice of Agency Rule-making Proposal, Chapter 12, Licensure of Manufacturers and Wholesalers

I write on behalf of the Insights Association, the leading nonprofit association for the marketing research and data analytics industry, representing companies in Maine like Digital Research in Portland, Drapeau Research Services in Biddeford, FUEL in Kennebunk, Gen Re in South Portland, and Libran Research & Consulting in Scarborough. We urge the Board of Pharmacy to clarify (with language proposed in this letter) that the prohibition on gifts to health care practitioners¹ exempts respondent incentives for practitioners participating in bona fide marketing research sponsored by pharmaceutical manufacturers and conducted by independent third party marketing research companies.

There is ample precedent for such an exemption at the state and federal level (see pages 2-3).

The law prohibits pharmaceutical manufacturers and wholesalers (or their agents) from offering or giving a "cash gift in any amount" or a "gift for which reciprocity is expected or implied" to a health care practitioner.

Unfortunately, this 2017 law has *inadvertently* banned respondent incentives for practitioners who participate in pharmaceutical marketing research studies, even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not aware of which practitioners participated. That is because pharmaceutical manufacturers' compliance departments take the most conservative reading of such laws: if marketing research incentives are not explicitly exempted or excluded, those compliance departments will assume they are prohibited as "gifts." Such has been the case across the industry since Maine passed this law two years ago.

What is marketing research?

Marketing research is not marketing – it is the systematic, objective investigation and analysis of people's opinions, attitudes and behavior.²

¹ L.D. 911 (HP 639), "An Act To Prohibit Certain Gifts to Health Care Practitioners," became law, without the governor's signature, on June 28, 2017. (2017 Public Law, Chapter 267, 32 M.R.S. §13759).

² Marketing researchers perform critical research to deliver insights to their clients; in the process, they sell nothing to research participants. Marketers, on the other hand, advertise and sell properties, goods or services directly to participants. These two functions are distinct and separate.

Most research studies are “blinded” to protect the research from bias. The respondents, and often the interviewers, are not told who sponsored the study. Sponsors normally do not know about or choose specific respondents and are not given access to respondents’ personally identifiable information. Most importantly, research industry codes, including the Insights Association Code, forbid researchers and their clients from marketing to research study respondents.³

Incentives for marketing research participation

We understand and appreciate the concerns about pharmaceutical manufacturers pursuing influence with health care practitioners through gifts, but the only influence sought through respondent incentives is to encourage a difficult to reach but highly important community to participate in research. Without a clear exclusion for bona fide marketing research (as has been granted before in the District of Columbia, Minnesota, Massachusetts, in the federal Physician Payments Sunshine Act, and most recently in California S.B. 790), this law has effectively ceased most marketing research studies of practitioners in Maine

Marketing research participation by practitioners is routinely tied to respondent incentives because of the high demands on and value of their time. Respondent incentives are clearly neither gifts designed to accrue influence, nor are they lavish. Rather, the payments are modest amounts (usually ranging from less than one hundred dollars to a few hundred per study) paid to compensate the practitioners for their time. Moreover, these incentive payments are not determined on an ad hoc or willy-nilly basis, but are instead subject to rigorous fair market value analyses performed by both pharmaceutical manufacturers’ marketing research staff and their outside research company partners.

A 2009 study of doctors found 9-in-10 physicians (92% of general practitioners and 93% of specialists) indicated that incentives play at least some part in motivating them to participate in marketing research. Less than 1-in-10 physicians (6% of general practitioners and 5% of specialists) said that they would participate in marketing research absent an incentive.⁴

Examples from other jurisdictions

What have other authorities done with respect to health care research and the payment of incentives to participating practitioners? Except for two states (Vermont and Maine), all permit such research and have little to no restrictions on marketing research incentive payments to these practitioners.

Clear exclusions for bona fide marketing research have been previously granted in:

- the District of Columbia,⁵

³ The Insights Association Code of Standards and Ethics for Marketing Research and Data Analytics requires in Section 1, "Duty of Care," that research and analytics professionals "Always distinguish between research and non-research activities so as to maintain public confidence in the integrity of research." They also must, "When engaging in non-research activities (for example, promotional or commercial activities directed at data subjects, including but not limited to advertising and direct marketing), do not permit any direct action toward an individual based on his or her participation in research without their consent." <https://www.insightsassociation.org/issues-policies/insights-association-code-standards-and-ethics-market-research-and-data-analytics-0>

⁴ Survey results explained at <http://www.insightsassociation.org/article/respondent-cooperation-how-big-impact-will-government-legislation-have-physician-surveys-us>

⁵ In 2007, Title III of the AccessRx Act (Chapter 18, Title 22) required payment reporting. In 2011, the DC Board of Pharmacy approved a marketing research exclusion, if: "(i) the market research is conducted by an independent survey research organization; (ii) the pharmaceutical client does not know the identity of the practitioners who participate in the research; and (iii) the payments are determined and made directly by the survey research organization."

- Massachusetts,⁶
- Minnesota,⁷
- the federal Physician Payments Sunshine Act,⁸
- California S.B. 790⁹, and
- New Jersey¹⁰.

⁶ In 2009, the Massachusetts Department of Public Health excluded respondent incentives from their state's reporting requirements. From the FAQs: "If a PMDMC [Pharmaceutical or Medical Device Manufacturing Company] hires a market research company to conduct a double-blind study of health care practitioners, where the health care practitioners are paid an honorarium by the market research company, but the PMDMC does not know which health care practitioners participated in the study and the health care practitioners who participated does not know what pharmaceutical or medical device manufacturing company was involved, is the information subject to disclosure? Answer: No. The regulations seek to create transparency around payments to health care practitioners by PMDMCs that may influence prescriber behavior. Where the health care practitioner participates in a market research study, but is not paid by the PMDMC and is not aware of the PMDMC involved, the payment need not be reported." See <http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pharm-medical-device-conduct-faq.pdf> at p. 14.

⁷ In 2010, the Minnesota Board of Pharmacy rescinded their long-standing ban on marketing research incentives, having determined that marketing research constituted a "genuine research project." From the FAQs: "Q. Under Minnesota law, is it appropriate to make cash payments to practitioners for participation in so-called "surveys" that are intended by pharmaceutical manufacturers to promote, market or sell a drug directly to those practitioners? A. No. Such practices would be considered commercial marketing activities, rather than bona fide market research (i.e. a "genuine research project") conducted by independent survey research organizations. Participation in marketing activities is not a "substantial service," nor does it involve a "genuine research project" as intended by the legislature. Therefore, cash payments to practitioners who participate in marketing activities are prohibited under the no gifts to practitioners statute." See https://mn.gov/boards/assets/FAQ%20Payments%20to%20Practitioners_tcm21-29333.pdf at p. 1.

⁸ In 2010, the federal Physician Payments Sunshine Act (part of the Affordable Care Act) excluded incentives from reporting requirements, and the exclusion was drafted specifically to pertain to blinded market research. Sec. 6002 of the Patient Protection and Affordable Care Act: "The term 'payment or other transfer of value' means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient." See <https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf> at p. 695.

⁹ In 2017, California S.B. 790 was amended to exempt respondent incentives to doctors for participating in pharmaceutical marketing research studies from the bill's proposed ban on payments, as long as the studies are conducted by a third party research company and the sponsoring manufacturers are not aware of which providers participated: From 150300 (a)(7): "A payment to a health care provider for participation in bona fide marketing research conducted by a third party, only if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating health care provider." And 150300 (c): "Bona fide marketing research" means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences, and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional, or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior." The bill died in 2018 and has not been reintroduced yet. http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB790

¹⁰ The New Jersey's regulation - "Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers" (N.J.A.C. 13:45J) – effective January 16, 2018, carved out independent marketing research from the restrictions and requirements for "agents" of pharmaceutical

Proposed language clarifying treatment of bona fide marketing research

We urge you to add the following to the proposed regulation:

For purposes of 32 M.R.S. § 13759(1), a “gift” does not include a payment to a practitioner for participation in bona fide marketing research conducted by a third party, if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating practitioner.

“Bona fide marketing research” means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant’s attitudes or behavior.¹¹

Alternatively, Maine could take the simpler approach of clarifying that independent third-party marketing research companies are not “agents” of a manufacturer.

For purposes of 32 M.R.S. § 13759(1), to the extent that a marketing research company does not engage in detailing, promotional activities, or other marketing of prescription drugs or biologics, such company, by definition, is not considered a manufacturer’s agent.

Either approach will protect an essential activity while still attaining Maine’s goals in the law.

Marketing research benefits patients and the public

Marketing research provides benefits beyond just the insights delivered to clients. For example:

- **Controlling health care costs:** Studies with doctors are actually an integral part of this new law’s goal to control costs. More and better marketing research results in cost savings as it can unveil potential flaws in drugs and treatment regimens before they pose a real risk to patients. Marketing research also helps focus limited resources on effective and necessary product and service development, technical support and education.
- **Preventing medical errors:** Marketing research helps measure comprehension of materials and differentiation of names among physicians for drugs, which can help prevent “medical errors.”
- **Ensuring patients get needed treatments:** Marketing research studies with health care practitioners about their patients’ compliance with treatment regimens help determine what causes patients to avoid or cease treatment and how to encourage compliance – which in turn promotes health and longer life, as well as reduced waste of medical resources.
- **Improving acceptance and adoption of needed drugs:** Marketing research studies of how practitioners will accept and adopt new drugs are crucial to the development of new lifesaving products. If a

manufacturers and from being defined as “promotional activities” on Page 39: “To the extent that a market research company does not engage in detailing, promotional activities, or other marketing of prescription drugs or prescription biologics, by definition a market research company is not considered a pharmaceutical manufacturer’s agent. In addition..., the Attorney General, upon adoption, is changing the rules to exempt research activities from the definitions of “bona fide services” and “promotional activity,” and to exclude from the bona fide services cap compensation for research activities.”

https://www.njconsumeraffairs.gov/Adoptions/cosado_011618.pdf

¹¹ This definition has been used at the federal level in the Research Fairness Act (H.R. 5915, proposed in 2012), available at <https://www.congress.gov/bill/112th-congress/house-bill/5915>, in amendments passed to a New Hampshire statute in 2014 on push polling (Title LXIII, Section 664:2 (XVII and XVIII)), available at <http://www.gencourt.state.nh.us/rsa/html/LXIII/664/664-2.htm>, and in California’s 2017 pharma bill, S.B. 790.

medication has poor odds of acceptance or adoption, the manufacturer may not invest in producing it, but may learn from the research how to counteract those deficiencies with an improved product.

- **Role-playing research yields results:** Marketing research studies involving doctor-patient role playing can garner unexpected findings vital to more than just the studies' sponsors. For example, studies have discovered that physicians often don't describe all available options to patients, even though they claim to do so in conventional research surveys.
- **Eliminating side effects for patients:** In one case example, marketing research with doctors directly led to the reformulation of a drug to deal with its side effects. The drug fights blindness, but resulted in burning red eyes for some users. Marketing research revealed that these side effects, which were not being perfectly reported, were keeping many patients from taking the drugs (on the required schedule, or sometimes at all). Reformulation removed the side effects, saved the drug, and saved many people's sight.
- **Improving public health in the Latino community:** Focus groups and in-depth interviews (IDIs) conducted with doctors on issues related to Type 2 diabetes in the Latino community helped manufacturers of diabetes medications and devices better tailor their communications and educational materials to make them understandable, clear, and free from dangerous mis-interpretations.¹²

On behalf of the Insights Association, we thank you for considering this clarification of the application of Sec. 1. 32 MRSA §13759. We strongly urge you to adopt one of the approaches outlined above or work with us on other potential solutions.

If you do not, practitioners in Maine may not be properly represented in research, leading to an inaccurate view of their and their patients' needs, which will hinder the development and delivery of medicines and services to address unmet patient needs across the state.

We look forward to talking with you and providing any more information you might require. If it would require discussion at a future board meeting, we'd appreciate the chance to present testimony.

Sincerely,



Howard Fienberg
VP Advocacy
Insights Association

¹² "Public Health Benefits of Marketing Research with Doctors: A case study from California." By Carlos Garcia. June 22, 2017. <http://www.insightsassociation.org/article/public-health-benefits-marketing-research-doctors-case-study-california>